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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,997	12/15/2000	James G. Keck	24743-2307US	5984
20985	7590	02/03/2005		
FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081			EXAMINER EPPS FORD, JANET L	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/601,997

Applicant(s)

KECK ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-14 and 58-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-14 and 58-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10-28-04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1635

## DETAILED ACTION

### *Petition to Correct Inventorship under 37 CFR § 1.48(b)*

1. Applicant's request to correct inventorship filed May 21, 2003 has been approved and entered. Applicants have appropriately provided an amendment to correct inventorship signed by a party set forth in 37 CFR § 1.33(b), and have paid the required processing fee set forth in 37 CFR § 1.17(i).

JOHN L. LEGUYADER *For Petitioner*  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

### *Response to Arguments*

2. Applicant's arguments with respect to claims 8-14, and 58-72 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-14, and 58-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following rejection was necessitated by Applicant's amendment to the claims filed 10-25-04.

5. The instant claims are drawn to a method of assigning a function corresponding to a phenotype associated with a product coded for by a nucleotide sequence of a sample nucleic acid, wherein said method comprises, "in the resulting host cells, analyzing changes in the phenotype to thereby assign a function associated with the product encoded by the nucleotide sequence of the sample nucleic acid."

Art Unit: 1635

6. The metes and bounds of the claimed method are vague and indefinite because the purpose of the method states "a method of assigning a function corresponding to a phenotype associated with a product," however the last step states that the function is assigned based upon analyzing "changes in phenotype." In the preamble of the method it appears that the function is associated with "a phenotype associated with a product," however the last step states that the function is actually assigned based upon "changes in the phenotype." The method appears to require knowledge of a particular "phenotype" associated with a product, such that when changes in that phenotype is observed, the function of the product can be established.

7. Claim 58 (and those claims dependent therefrom) recites the phrase "directionality of expression," the term "directionality" in claim 58 is a relative term that renders the claim indefinite. The term "directionality" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US Patent No. 6,355,415 B1) in view of Gudkov et al. (US Patent No. 5,753,432).

It is noted that the following prior art is applied to the extent that the instant claims are interpreted as encompassing wherein gene function is assigned based upon the observation of

Art Unit: 1635

“changes in the phenotype” of cells expressing one or more members of an oligonucleotide family, in comparison to the phenotype of cells not expressing one or more members of an oligonucleotide family.

Wagner et al. teach methods to define gene function. In a particular embodiment of Wagner et al., ribozymes are transiently or stably transfected into a host cell, the effect of ribozyme expression on the transfected cell (e.g., fertilized egg cell, cell derived from a cell line, plant protoplast, callous cell, protocorm-like body cell, etc.) and/or progeny (e.g., embryo, fetus, adult animal, plant, subsequent generations of a cell line, etc.) derived from this cell is determined in relation to controls which are not transfected with the expression vector, or which are transfected with an expression vector that encodes an RNA which does not cleave the substrate RNA. For example, morphological and pathological changes may be determined using methods known in the art such as by visual inspection, histological staining, electron microscopy, magnetic resonance imaging (MRI), computerized tomography (CT) scans and the like. Morphological changes as a result of ribozyme expression indicate that the gene whose transcript is cleaved by the ribozyme is important in the formation of the structure whose morphology is altered by ribozyme expression. In a preferred embodiment, the observed change is morphological. (see col. Col. 29). Absent evidence to the contrary, the methods of Wagner et al. used to identify morphological and pathological changes would identify wherein the function of associated with a particular product is associated with changes in enzyme activity or protein synthesis (i.e. histological staining), expression of a biological factor, or a regulatory effector function.

The invention of Wagner et al. may also be considered to encompass the use of antisense nucleic acid molecules to inhibit the expression of genes for the expressed purpose of determining gene function, since the structure of the ribozymes described by Wagner et al. include two antisense oligonucleotide regions which function to bind the substrate nucleic acid (see page 17, line 58). Therefore, the ribozyme constructs of Wagner et al. may be considered to encompass antisense nucleic acid. Transfection of the ribozyme constructs of Wagner et al. is not limited to the use of plasmids as vectors. Other expression vectors contemplated to be within the scope of the invention include, but are not limited to, recombinant bacteriophage, cosmid DNA expression vectors, yeast expression vectors, virus expression vectors and the like (see col. 25-26). The invention of Wagner et al. may also encompass the use of a retroviral vector to infect cells with the nucleic acid constructs encoding the inhibitory nucleic acid molecules of the invention (see col. 10, line 24).

Wagner et al. does not provide specific guidance for amplifying and expressing the oligonucleotide constructs of the instant invention in cells without the use of bacterial cloning steps. However, Gudkov et al. provide methods for designing a retroviral library of nucleic acid fragments to be delivered to eukaryotic cells to test or determine the ability of these nucleic acid fragments to function as genetic suppressor elements (GSE) (see col. 10-12). The methods of Gudkov et al. essentially comprise methods for identifying gene function since the ability of the putative nucleic acid molecules to function, as a GSE is unknown prior to testing.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the teachings of Wagner et al. with the teachings of Gudkov et al. in the design of the instant invention. One of ordinary skill in the art would have been motivated to

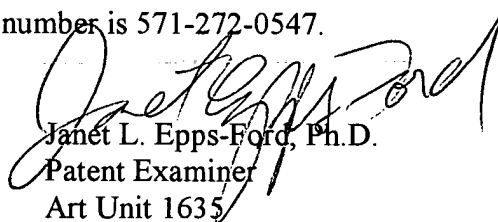
Art Unit: 1635

make this modification since Wagner et al. expressly states that their disclosed methods for determining gene function may encompass wherein the transfection method comprises the use of retroviral vectors, and the teachings of Gudkov et al. are specifically designed to deliver nucleic acid to cells using retroviral vectors with the express purpose of determining their ability to alter a phenotype of the transfected cells.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0547.

  
Janet L. Epps-Ford, Ph.D.  
Patent Examiner  
Art Unit 1635

*JLE*

February 1, 2005